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Will The Future Bring Growth And Sustainability?

Distributors Rethink Financing, Services and Staff Development

Publication of the 2014 figures of Brenntag, DKSH and IMCD has shown that last year was a good one for chemical distributors. Sales growth was moderate, but measures to increase efficiency paid off, and the companies showed improved results. Mid-sized, privately owned distributors are not obliged to publish data, but when asked in private, they will mostly agree that business in 2014 was indeed quite good.

But what will the future bring? The theme of this year's FECC Congress is "Towards a Sustainable Future," and the speakers will address topics such as "Success Factors in the Chemical (Distribution) Industry" or "How to Plan for the Long Term?" In this context, it is worthwhile to review where the industry is headed and what individual companies can do to become or remain successful.

Günther Eberhard, managing director, DistriConsult

Quoted Distributors Bring More Transparency

Last summer IMCD joined the ranks of the few publicly listed chemical distributors. The initial public offering at the end of June on the Euronext exchange in Amsterdam was oversubscribed. The shares are trading about 50% above the offering price.

Successful IPOs and the growing list of quoted distributors are certainly attracting more attention to the industry as a whole, as more asset managers and other institutional investors have taken an interest in the industry. The larger companies are now getting regular coverage from analysts at banks and other financial institutions or even rating agencies, such as Moody's or Standard & Poor's, for the bonds they have issued. This brings transparency but also pressure to perform and the need for sound compliance and good governance.

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What Else Will 2015 Bring?

According to the International Monetary Fund, global growth is forecast to rise moderately in 2015-16, from 3.3% in 2014 to 3.5% in 2015 and 3.7% in 2016. Unfortunately, Europe is more subdued, with an expected growth rate of only 1.2%, despite certain "supporting factors" such as a lower oil price and a depreciation of the euro.

As the chemical industry is feeling the effect of the significant decline in crude oil prices since last summer, distributors cannot escape these developments. Headline sales might therefore suffer somewhat in parts of the industry. However, gross margins tend to move less strongly than the underlying product price levels, and measures to increase organizational efficiency should help the bottom line.

The devaluation of inventories can cause problems, when sudden negative price swings need to be absorbed and companies have gone long on the products they store. The strengthening US dollar will also influence companies that import into Europe and will make dollar-denominated purchases more expensive. With these crosscurrents, companies do well in assessing their own specific situation and taking appropriate action. Prudent management and a strong underlying financial position will help companies maintain and even improve their market positions.

And What About M&A?

The recently announced sale of Azelis by 3i to global private equity house Apax Partners is one of the larger deals in the history of the industry. 3i had been invested in Azelis since late 2006. It appeared that they were running out of steam a bit. Apax Partners, on the other hand, is new to chemical distribution, and it will certainly bring some fresh views to the business. As the announcement of the transaction clearly spelled out the global ambitions and the international growth plans, this new investor can be expected to aim high, maybe for Azelis' IPO in a few years.

But medium-sized distributors also conclude transactions. The main drivers, our analysis of 2013-14 data suggests, are gaining access to new applications and broadening the geographic coverage, mostly within Europe.

Financing Growth

To finance their growth plans, companies typically rely on their own free cash flow, particularly when the owner families have only a few members and a strong philosophy of reinvesting a large portion of the profits back into the business.

Or companies can access the capital markets. However, this is often a viable route only for larger, listed or private-equity-backed companies. When private companies have an ownership structure in which some family members require a steady dividend stream, alternative forms of financing must be found.

Recently, Dutch specialty-ingredients distributor and food- and feed-additives blender Barentz International has tapped the financial markets by obtaining "growth capital" from an unnamed family office as a minority equity partner in the company. Several examples from Germany show that the use of mezzanine capital seems to be getting a good reception. Only a few weeks ago, Overlack obtained a tranche of growth financing from Hannover Finanz, in the form of a convertible loan. Biesterfeld obtained the same form of financing in January 2011. That particular loan, provided by the same investor, was converted into a minority shareholding (28.6% of the capital) in the holding company of the group last October. But also smaller distributors, such as Velox, have resorted to participation rights as a way to finance growth initiatives. Taking on mezzanine capital appears to be a lot more palatable than an outright sale of a minority share of one's family-owned company to a financial investor.

Services As A Differentiator

A number of distributors try to differentiate themselves from their competitors by providing a selected range of services besides the chemical product as such. Typical examples are

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Refreshing chemical distribution

application laboratories, which are mostly found in cosmetics/personal care, food and nutrition, and pharma, but also in technical applications such as paints and coatings, homecare/industrial and institutional cleaners, or adhesives.

The aim is to provide a body of product and application knowledge, helping to develop research formulations and explaining new application opportunities or product features, in order to position a premium product range. Another task is competitive matching – to get products into existing formulations with ingredients and additives from other suppliers. The laboratories and the standard equipment items are operated by the distributor's technical staff, tests and developments requiring more specialized analytical equipment and skills are outsourced to third-party service providers.

Laboratory services are typically used as a marketing and sales tool and not charged for separately. In that sense they are "freely available," as a large distribution group claims on its website. But some distributors are discussing whether they should charge a fee for the service, separate from the product price. The key question here is the market's readiness for this. While this may generate an extra contribution margin, it leads to questions of positioning of the offering and the liability assumed, e.g., for the accuracy and validity of test results, which have to be addressed beforehand.

Another service element offered by some distributors, which has gained a lot of attention over the last few years, is the provision of regulatory advice. In Europe, where a whole industry of expert consultants developed in the wake of REACh (Registration, Evaluation, Authorization and Restriction of Chemicals), this may not be a unique offering. But in other geographies, where tighter chemical regulation is more recent and often available only in local languages, such an expertise is very valuable, particularly to chemical producers who are planning to sell locally, either direct or via a distribution partner. DKSH, for example, has built up a sizeable team of experts, both in Europe and in Asia. The availability of such resources could very well be one of the deciding factors when suppliers select a distributor.

When principals contemplate working with distributors as a channel to market, one concern is often the fear of losing touch with the market. Distributors can alleviate that concern by offering regular reporting, particularly of project activities. This may require the investment in a suitable CRM system, and, where this is already in place, some modification to the existing setup, to implement an automatic interface. This is often supplier-specific, so projects in that field can be quite time-consuming and challenging. However, when it's all up and running, the ability to generate informative and meaningful reports at the push of a button never ceases to impress.

Professionalization Of Staff

A number of distribution companies have reached a size where the need to put adequate management structures in place can no longer be neglected. Only then can the required level of "unité de doctrine" be ensured and complexity managed efficiently.

Systematic human resources management becomes an ever more important success factor. Training and

development of management can no longer be outsourced to the chemical industry, in the hope that when the need occurs, senior management candidates can be searched for, identified, selected and hired from the outside. Distribution of chemicals is fundamentally different from manufacturing of chemicals: It is about building and maintaining relationships versus efficiently utilizing assets, to use a simplified comparison. The distribution industry must develop its own management pool more systematically than in the past, in order to be able to drive further expansion.

In this context, it has been interesting to see that Brenntag has recently appointed the group's first global human resources director. It might not be long until other large distribution groups with global aspirations will follow.

"Mind the Gap — In the Middle"

While industry consolidation will no doubt continue, large multicountry or even global distributors will coexist and compete with numerous local players, only active in a specific country or geographic region. Both groups can be successful, depending on how good they are at meeting the needs of the often-global principals and the mostly local customers they serve.

Application Laboratories & Technical Competence Centers

Company	Pharma	Food & Nutrition	Cosmetics / Personal Care	Household / I&I Cleaning	Paints & Coatings	Others
Azelis	x	x	x		x	
Bodo Möller Chemie						Adhesives (Materials Technology)
Brenntag	x	x	x	(x)	x	Lubricants, Oil & Gas, etc.
DKSH	x	x	x			
IMCD	x	x	x	x	x	
NRC			x	(x)		Rubber
TER GROUP			x		(x)	
Univar		x	x	x	x	Agrochemicals

Note: Selected distributors only
Source: Company website & press release, DistriConsult analysis

The large players, being listed, private equity or family-owned, will continue to grow as they roll out their business models further. Such a growth trajectory is not without pitfalls, as the local customer contact still counts a lot and must be combined with measure to reduce complexity and maintain or enhance efficiency. But financial strength and prudent management enables them to further expand their position in the industry.

Smaller companies, who typically enjoy close customer contacts and often deep insights into the workings of their target industries, must work on their attractiveness to leading producers of chemicals. Large principals are expecting a level of service that requires investments in infrastructure and people. Small companies must decide where they want to compete and then focus on defendable niches. Only then can they afford to fund the growth projects and the infrastructure required, be it in a laboratory or a modern CRM system that can generate timely project reports to support customers and enable close cooperation with suppliers.

But there are also companies that can best be described as "caught in the middle." These are distributors that are no longer operating only in attractive and defendable niches or that are financially and management-wise not strong and confident enough to grow by attracting new suppliers or moving into adjacent geographic markets. Owners and managers of such companies need to make some really hard choices in order to stay clear or get out of the danger zone. And for some, this may make it sensible to exit certain industries or countries or even to sell out altogether, so that a combined business under different ownership has a more sustainable future.

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Caught In The Middle

Distributors Must Prove to Customers and Principals That They Are Crucial to the Supply Chain

In May 2014, Dr Neville Prior, Chairman of the Cornelius Group, took over as president of the European Association of Chemical Distributors (FECC). Speaking about his appointment, Dr Prior said, "It is now my turn to lead the association into the next phase, without losing the essence of FECC." Dr Michael Reubold asked him about the current state of the chemical distribution industry, his outlook for the future, and the goals he has set for his presidency.

Dr Neville Prior, president of the European Association of Chemical Distributors (FECC)

CHEManager: What is your personal perception of the European (or global) chemical distribution market in terms of market size and the emergence of new opportunities?

Dr Prior: The chemical distribution sector is large. We believe it to be around €170 billion globally, with about €30 billion in Europe. If one looks at growth rates, then the emerging markets show double-digit growth, whereas we do not see this in the mature economies of Europe and North America. Overall growth rates are between and 6% and 7%, which of course gives rise to new opportunities each year.

Do you expect growth opportunities for chemical distributors due to an increasing market volume or will we rather see a shifting of market shares via industry consolidation in a stagnant market?

Dr Prior: The market continues to grow, and we see that manufacturers are increasing their use of distributors. This gives opportunity to those distributors that can match their strategies to those of their principals, or that can fulfill a service in a specialized niche. Industry consolidation will continue where it makes sense, but the industry is still highly fragmented, and will continue to be so.

What will be the major trends influencing the direction the chemical distribution industry will take in the future, and what do you see as the biggest challenges that the industry will have to deal with?

Dr Prior: There will be trends going in two directions. One will encompass the large volume, less specialized chemicals, and will necessitate that distributors offer a cost-effective service to principals, whilst meeting all health, safety and environmental requirements. The second will be in the field of specialties, and will require distributors to not only offer sales expertise, but to go further in creating innovative solutions for principals and customers alike. Distributors will need to invest in technical functions, and added value facilities such as blending and compounding.

> "In reality, size is not the relevant factor. What matters is capability and expertise."

The acronym VUCA is frequently being used to describe the volatility, uncertainty, complexity and ambiguity of market conditions also in the chemical and pharmaceutical industry. How does the VUCA world affect chemical distributors?

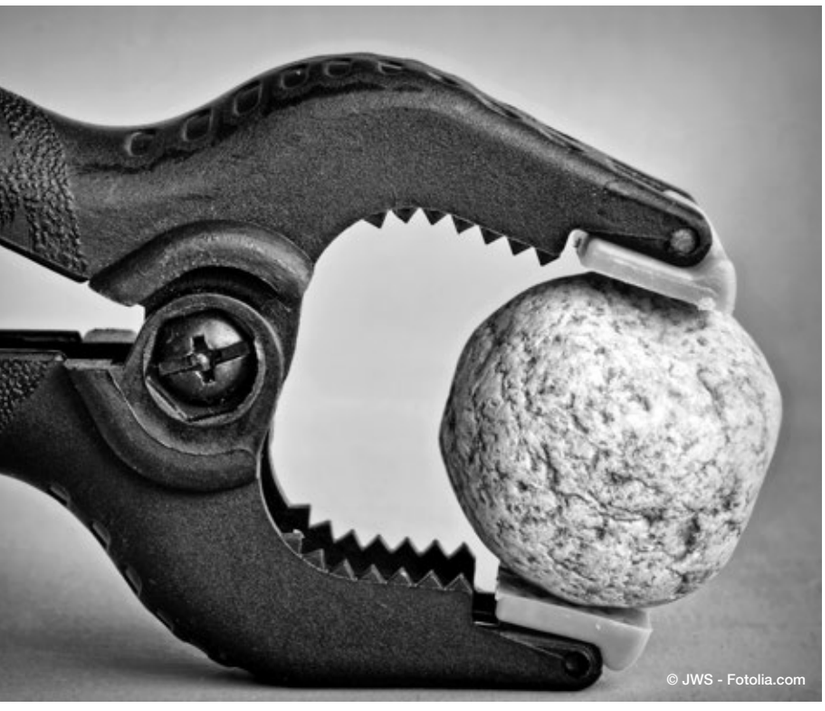
Dr Prior: In common with other businesses, distributors are affected by all of these things. The positive thing for distributors is that generally they have very flexible business models, and are able to adapt to rapidly changing conditions. It is no coincidence that the industry has come through the recent global financial crisis in a strong position, and we would see this continuing for the future.

How will chemical distributors have to adapt their business models or strategies in order to participate in the future growth of their principals?

Dr Prior: This is all about aligning strategies with those of the principals. We see manufacturers looking to work more and more with good distributors. No longer can a distributor simply act as a sales conduit. They have to share appropriate information and work in partnership. Distributors have to add value in many ways, including managing supply chains; working with principal and customer alike to create innovative solutions; ensuring good health, safety and environmental practice; and providing repacking, blending and other added value operations. Distributors will need to invest in resource and relevant assets where necessary.

As the link in the chemical supply chain that connects producers with buyers, distributors do often feel (financial) pressure from both sides. How can they ensure their fair share of the business?

Dr Prior: Distributors may feel that they are "caught" in the middle, being squeezed from above and below. However, providing that they can show their value to customers and principals alike, then they have an



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important part to play in the supply chain. The skills of distributors are often unique, and the ability to supply "baskets of goods" alongside expertise in products and services, can give them a strong position with many customers.

As in the chemical industry, small and medium-sized companies are forming the majority of the distribution industry. A question that is therefore constantly being discussed is, "Does size matter?" Does it matter?

N. Prior: In reality, size is not the relevant factor. What matters is capability and expertise. Of course, all principals want to work with financially secure partners, but often, the smaller distributors have unique knowledge and infrastructure that gives them a strong position in the market. There is and will remain a place for local, national, regional and global players.

For some years now, "sustainability" has been one of the buzzwords in the chemical industry. You chose "Towards a Sustainable Future" as the theme of the FECC Annual Congress 2015. One of the session titles is "Sustainability, Putting It in Perspective." In your opinion, what does sustainability stand for?

N. Prior: There are many opinions over sustainability, even so far as what it means! In my view, we all have a duty of care towards our employees, local communities, the environment and our industry. That aside, consumers are demanding "responsibly produced goods" and customers are constantly working towards ever more sustainable solutions. Not only is this morally driven, but also consumer and government driven: It is definitely the future.

> "The skills of distributors are often unique."

What goals have you defined for yourself to achieve during your presidency?

N. Prior: FECC has an enviable past, and I want it to have a sustainable future, so that it can continue to be the voice of our industry in Europe. We wish to increase our membership both in terms of company and national association members, and to this end we have welcomed several new members in recent months. Our services need to be relevant to our membership, and we continue to review these on an ongoing basis. It is important that we continue to drive forward Responsible Care and sustainability in Europe, and we will continue to work with Cefic – the European Chemical Industry Council – on this topic. Clearly we will continue to work with regulators to ensure that future legislation is appropriate to the wider community and our industry alike.

www.fecc.org

Changing Hands

Azelis Enters Next Phase under New Ownership

In February, Atlas, the holding company of the Azelis Group announced the sale of the specialty chemicals distributor to global private equity firm Apax Partners. Since 2007, when private equity investor 3i acquired a majority stake in Azelis, the company has transformed from a decentralized European business into an integrated group with a turnover of €1 billion and facilities in more than 35 countries worldwide. Apax Partners said they intend to continue Azelis' strategic focus on growing the business through ongoing development of its product portfolio and continuing to extend its global reach, both organically and through acquisitions. Azelis CEO Dr Hans-Joachim Mueller explained to CHEManager's Dr Michael Reubold what the new ownership means for Azelis' future strategy.

CHEManager: Dr Mueller, before talking about the future, could you briefly summarize the milestones Azelis achieved in the past years under the ownership of 3i?

Dr H.-J. Mueller: 3i really supported us in enabling our reorganization and providing the means to deliver rapid and sustainable growth over the last years. When 3i took over Azelis in 2007, they aimed to establish a pan-European platform for the industry segments Azelis was serving at that time. So, until 2011 they undertook quite an acquisition spree. By then all the white spots, except for a few, were covered by Azelis affiliates throughout Europe. Also 3i pressed hard to bring Azelis on one ERP platform. This was a major effort, because as you can imagine, all these companies had different ERP systems and to get a consolidated view on the business was really difficult back then. But until 2009 Azelis still was a confederation of companies, not only with regard to the ERP system, but also with different names, reputations and the ways they were doing business. So, the next focus was to develop one Azelis corporate identity and create one Azelis brand. Today, we are Azelis and we share one common set of values and aspirations all over the world.

> "The trust of our principals really is key for us."

In 2012, when I joined the group, the business was not living up to the expectations because in addition to economic factors, we had too much internal focus and had lost some focus on principals and on customers. Also, acquisitions done at the end of 2011 had resulted in some dis-synergies for the business. With the support of 3i we started to build a strategy. First, we defined the lateral value chain, (what products we needed and where, coupled with the associated services and technical staff needed to support them) and then we targeted strategic principals. Based on this concept, in 2013, we built a strategy for the industry segments we are serving, which, in 2014, we mirrored into the different countries and aligned with the overall strategy.

From 2011 to 2013 Azelis' sales revenues decreased from €1.2 billion to below 1 billion. Was that mainly due to divestments?

Dr H.-J. Mueller: Yes, this was due to the fact that Azelis divested activities such as the composites business and the polymer business. Also, we de-emphasized the commodity arena because we are not a commodity player and don't want to be one. There are completely different rules of the game in the commodities compared to the specialties business.

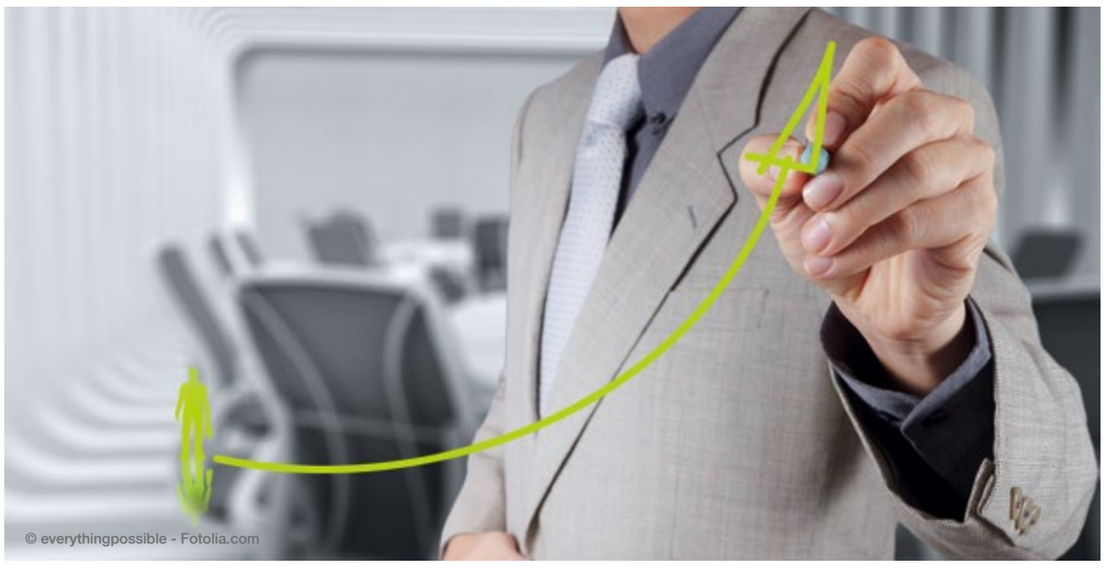
Dr Hans-Joachim Mueller, CEO, Azelis

Over the last two and a half years we have put a strong focus on rebuilding the trust of our principals. This really is key for us. It is important to gain new principals, but we have to serve those who entrusted us with their business first. We have decreased general and administrative expense by 30% since I came, and year after year, have added experienced frontline technical sales people into the market - many joined us from the particular industry segment that they are now lead. And we have built 15 new applications labs to support our partners in developing individual solutions.

Over the last two years our profitability has grown mostly by focusing on specialties and services, and we are also growing top-line again.

What will your growth strategy look like under the new ownership of Apax Partners?

Dr H.-J. Mueller: We will not completely change our direction into what we are doing. Today, we serve more than 20,000 customers in the coatings, chemicals, rubber & plastic additives, food & health, animal nutrition, pharma and personal care industries. I am not a big fan of transformational acquisitions, because I do believe that as a specialty chemical distributor you would potentially buy yourself a lot of dis-synergies. So we will only make bolt-on acquisitions to enhance our existing platform in Europe for segments and markets where we feel that the company we are looking at, represents a beneficial fingerprint. Because then there is a smaller risk of losing something once you try to integrate.



When it comes to Asia, the situation is a little bit different as my readiness to acquire small players in Asia is rather cautious, because our board, shareholders and principals expect us to be very prudent when it comes to business practices. And from my years in Hong Kong I know that if you have a business which is just a small family shop in Asia you can always run the risk that it is not compliant. So this is something I try to avoid. If we do bolt-on acquisitions in Asia, they will be planned and looked at very carefully. We would follow a so-called tag-along approach, meaning that a blue-chip principal of ours in Europe will entrust its Asian business to us. This is how we entered into China, and it worked very well. Today we have over 70 people at 5 locations in China. We did the same in Japan and in Vietnam. This is how we will drive growth with Apax. There won't be a disruption of the strategy, but we will have a little bit more freedom when it comes to doing bolt-on acquisitions.

Speaking about geographies, Africa is pretty high on our agenda and we are about to open our first office in Morocco. We have hired people to serve the market there. We obtained a business entrusted from a blue-chip principal we are working with in Europe. We will then move further into the market, into Algeria, and we also want to move into Nigeria, Angola, and Kenya.

What is your vision for the future?

Dr H.-J. Mueller: Our strategy for growth is centered on the ambition to further build a lateral value chain in the market segments we serve. This clear vision is currently being implemented throughout the company, both locally and internationally. This new phase of our development will improve our future business prospects, facilitate expansion plans and accelerate growth, which – as I said – may include targeted acquisitions where needed.

Our business approach, first and foremost, is all about the technical service element: being in front of customers with the technical and application expertise to clearly explain our principals' products and present the synergies our unrivalled specialty product portfolio can offer – at any stage of product development from concept through to manufacture. This is what individual principals cannot do because they are usually focusing on their own particular products. It is very much about having a coherent approach to the market supported by application labs.

And certainly it is all about growth. So we will continue hiring technical sales people. We will stay very lean on the G&A side. By 2020, we will have delivered an excess of 10% CAGR for the business with regard to the top line. And we are currently on a very good track with that.

Apax said that they will support us in further establishing a position as a leading global distributor, continuing to strengthen our proposition for principals and customers, embarking on a phase of strong international growth in order to achieve the full potential of the business over the years ahead. Obviously, Apax at some point will also look into what to do with the business, and the exit strategy could either be selling Azelis to another private equity owner or doing an IPO, but this is pure speculation at this moment in time.

www.azelis.com

Toward a Sustainable Future

Chemical Distribution Industry Continues Seeking Ways to Add Further Value

Chemical distribution is and will continue to be a vibrant and professional industry that has demonstrated its strength by overcoming challenges and emerging intact despite the economic context of recent years. Without a doubt, the industry plays a key role in the supply chain and adds value to the manufacturers with which distributors work closely and to the customers they serve.

Dr Uta Jensen-Korte, director general, FECC

In response to these realities, the chemical distribution industry has to continue seeking ways to add further value and to answer customer demands. The legislative burden on the industry is ever increasing. While we welcome the initiatives of the European Commission to improve the regulatory landscape, it is also vital that distributors are fit for purpose, ensuring they meet all legal and environmental requirements.

A revised four-year strategy was approved at the extraordinary general assembly meeting at the membership meeting in November.

The strategy is established to guide the actions of the European Association of Chemical Distributors (FECC) between 2015 and 2018. Under the slogan "We are THE voice of our industry," the strategy presents objectives and a value proposition as means to achieve a vision for FECC. The vision is for our association to "become THE opinion maker within our industry so that we are the natural partner for our members, European institutions and stakeholders." The strategy objectives mark the way for our association to:

- ☐ Promote the chemical distribution industry
- ☐ Represent FECC members' interests on European and global levels
- ☐ Ensure a sustainable business environment for distributors
- ☐ Develop chemical distribution as an added value partnership in the supply chain
- ☐ Foster cooperation with relevant sectors in the chemical supply chain
- ☐ Drive Responsible Care and sustainability
- ☐ Support the national associations

The integration of these principles with FECC's vision led to four basic values: expertise, advocacy, networking and communication. The four categories have working topics that are related to FECC objectives. The execution of the strategy lies mainly with the FECC working committees and the secretariat.

FECC's efforts continue to support our members with high quality services through our expert committees and by organizing specialized workshops. They cover topics such as regulatory and quality standards related to food, cosmetics and excipients; how to comply with food safety as a chemical distributor; or the workshop of FECC with CEFIC, Eurometaux and DUCC about "how to classify mixtures under CLP – be able to check your software results" to support our members' preparation for the classification, labeling and packaging (CLP) deadline in June.

A major achievement of the association's committee work has been the launch of a model distribution contract. Such a model contract will support our members in their discussions with their suppliers.

The FECC model contract contains the substantive rules for a distribution contract, i.e., the main rights and obligations of the parties, the remedies for breach of contract, and the general rules that apply equally to both parties, among others. It also contains the boilerplate clauses broadly accepted in commercial contracts.

The model contract can be viewed as a general flexible framework and needs to be adapted to the nature of each contract as well as to the specific requirements of the applicable national law.

The Responsible Care Committee worked on the revision of the FECC European RC program to improve clarity and to implement criteria enabling the evaluation of quality assessments performed with alternative third-party validation tools. The revised program was launched at the beginning of this year.

REACh (Registration, Evaluation, Authorization and Restriction of Chemicals) remained important amid the preparation for the 2018 registration deadline and the dedicated support to small and medium-sized enterprises (SMEs), the authorization process, extended safety data sheets (SDS) issues and supply-chain communication. In this context, FECC advocates for the simplification and reduction of the overall costs of the process. FECC is actively involved in the Expert ▶

Sustainability is a Forward-Looking Topic

Thomas Arnold, CEO, Biesterfeld

With effect of April 1, 2015, Thomas Arnold has taken over the role of CEO at Biesterfeld from Birger Kuck who retired after eleven years as CEO and a total of 35 years with the company on March 31, 2015. Prior to this appointment Arnold has been member of the board of Biesterfeld and Managing Director of Biesterfeld Spezialchemie. He joined the internationally operating, fast-growing distributor of plastics and chemical products in 2013 and was appointed to the board of Biesterfeld in July 2014. The Biesterfeld Group stands for a corporate culture that is characterized by the principles of constructive, amicable and transparent cooperation. Dr. Birgit Megges asked Thomas Arnold about the role of sustainability in the company's everyday business.

CHEManager: Mr. Arnold, how is sustainability reflected in your company or business strategy?

T. Arnold: Sustainability is a forward-looking topic and, of course, it is an important aspect of our business strategy and our daily business. We actually fulfill the aspects of the 'Together for Sustainability' initiative TfS, but TfS does not meet all our requirements. This is the reason why we decided last year to join the UN Global Compact with its ten principles of human rights, labor, environment and anti-corruption. In addition, we joined the Global Reporting Initiative. At the moment, we are working on our first sustainability report.

What importance does sustainability have in your relationships with principal and customers?

T. Arnold: As a family-owned company sustainability is a natural factor of our business strategy as well as long-term partnerships and a family atmosphere. For us, it includes environmental, social and economic aspects. For this reason our sustainability concept is based on different standards. Next to our code of conduct we decided to join Responsible Care, UN Global Compact and Global Reporting Initiative. It is natural for us to consider human rights, labor, environment and anti-corruption. Overall, the importance of sustainability grows noticeably, essentially caused by increasing customer demand.

> "For us, sustainability includes environmental, social and economic aspects."

Toward a Sustainable Future

◀ Network on Exposure Scenarios (ENES) platform set up to promote workable solutions and practical improvements for exposure scenarios implementation.

To evaluate the regulatory landscape of Europe and the competitiveness of the chemical industry, the European Commission launched a high-level study with the aim to analyze cumulative costs of the relevant EU legislation that specifically affects the chemical industry, including: chemical legislation, energy legislation, industrial emissions and processes legislation, workers safety legislation, customs and trade legislation, transport legislation, consumer health legislation, and chemical product legislation.

In addition, the study will seek to provide an initial comparison (quantitative, where possible) of costs incurred by the chemical industry in Europe versus costs of main competitors on the world market. The distribution sector might not be the core sector covered by this study, but taking into account its relevance distributors will be consulted.

We intend to help our many stakeholders understand the global marketplace and the regulatory framework surrounding it.

On a positive note, the past year has seen our association gain three members: CG Chemikalien, 2M Holdings and Millchem, our first member from Africa. This year we are proud to welcome Safic-Alcan from France, Interallis from Cyprus, PolymerTorg, our first member from Belarus, and Synergy from Greece as new members. All of them are true success stories in the chemical distribution industry. Membership development remains a priority to strengthen our position as the European voice of the chemical distribution industry.

FECC will continue working to ensure that the chemical distribution industry is sustainable and that our members remain fit to tackle the challenges of the future.

Therefore, the theme of the FECC Annual Congress in Athens, Greece, May 6-8, aligns with the motto of FECC's 2015 business plan "Moving Ahead, Building a Sustainable Future."

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Together for Sustainability

Chemical Company Initiative for a Greener, More Humane Value Chain

Sustainability is not a new topic for the global chemical industry, which has a long-standing track record of putting such principles into practice. Along with creating clearly understandable and uniform standards for its own companies, the industry has also traditionally extended a helping hand to others along the value chain. To take its sustainability pledge to an even higher level and help meet new challenges, six European companies in 2011 joined in the Together for Sustainability Initiative (TfS), which now boasts 12 members in Europe and the US

From Responsible Care – the industrywide global initiative created in 1985, now running in 52 countries and accounting for nearly 90% of global chemical production – to the International Council of Chemical Associations (ICCA)'s Global Product Strategy stewardship program and beyond, there is no need to look far for examples of the chemicals sector's dedication not only to the development of new products, but also its willingness to accept responsibility for their safe application.

Building On Experience

As the supply chain becomes increasingly global, the number of hands – or machines – needed to manufacture a single chemical product has grown significantly over the past years, giving rise to the need for improved and more transparent ways of doing business both at home and abroad. By participating in TfS, players in such important emerging markets as China or India stand to benefit from the experience already gained by established multinational companies in dealing with the EU's REACh (Registration, Evaluation, Authorization and Restriction of Chemicals) scheme or the reform of the Toxic Substances Control Act (TSCA) analysis program in the U.S., for example.

Building on established principles such as those set down in its own Responsible Care program as well as in the UN Global Compact on sustainable supply chains, the original six members of Together for Sustainability – BASF, Bayer, Evonik, Lanxess and Henkel, along with Solvay of Belgium – began implementing their new supply-chain management tool in 2012. Within the first two years they were joined by AkzoNobel and DSM of the Netherlands, Clariant of Switzerland, Arkema of France, and German chemical and pharmaceuticals producer Merck.

The number of companies joining the procurement-led initiative has continued to grow. The newest European member is Germany's Wacker Chemie. Early this year, US multinational Eastman joined, as part of an effort to draw into the fold American chemical producers with business overseas.

From Sustainability to Human Rights

Toward the goal of cutting down on bureaucracy and unraveling red tape, TfS operates with industry-specific questionnaires and audit forms specially designed to assess supply companies' performance. The uniform paperwork builds on sustainability standards established by the International Labor Organization (ILO), the International Organization for Standardization (ISO), Social Accountability International (SAI) and other international authorities.

The financial side of the process is steered by outside experts such as international auditing giant PricewaterhouseCoopers (PwC), Germany's DQS and EcoVadis, a Paris-based rating company dedicated to sustainable supply-management evaluation. The rating specialists have been integrated into the platform to carry out supplier evaluations that encompass issues from management, environment, health and safety to corporate governance, labor and human rights.

Both procurers and suppliers stand to profit from the web-based platform, the TfS initiators say. As audits and evaluations and the subsequent scorecard ratings are published online to be viewed by all participants, there is no longer a need for company-specific evaluations, even if onsite checks of production plants, warehouses and office buildings still serve to verify the virtual information gleaned.

Streamlining The Standards

Rather than filling out multiple forms, suppliers to TfS member companies must go through the process only once. The common standards also relieve chemical producers of the chore of obtaining separate sustainability assessments or audits from all of their many suppliers. Risk matrices help the producers identify those suppliers with a high sustainability risk potential.

The dream of TfS is eventually to see companies along the entire value chain operating on a single binding sustainability platform, and the chances of this vision becoming reality are looking increasingly likely. Suppliers in China, India and Brazil are now coming firmly into focus. To move the process forward more quickly, the scheme's initiators also hope to draw international chemical industry organizations into the operation. To this end, in 2014, TfS held a Supplier Day in Shanghai, China, and also conducted training sessions in both China and Brazil.

In China, the sustainability drive's members are working together with East China University of Science and Technology in Shanghai. Within the next five years they hope to be able to train the employees of around 2,000 suppliers in the common standards. In Brazil, the initiative member is following the same approach. Here, Espaco ECO Foundation is a partner.

The number of evaluations and 93 audits under TfS has steadily grown since 2012. Last year alone, the initiative carried out 2,505 evaluations and 93 audits. In cases where an analysis shows a need for further improvement, the producers and their auditors step in to help the client meet the established requirements and later carry out a second evaluation.

Along with improving the quality of supply, upholding environment standards and safeguarding the rights of supply company employees – the initiative, for example, will not do business with Third World firms employing child labor – Together for Sustainability also has a distinctly positive effect for large multinational chemical players in showcasing to an often critical public the high standards they and their suppliers follow.

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Two Names – One Sustainability

Chemical Industry Should Seek to Unify ESAD, TfS

In 2011 six European chemical companies joined to create the "Together for Sustainability" initiative (TfS), which now has 12 members in Europe and the US (compare article on the opposite page).

The companies organized in the German Chemical Distribution Association (Verband Chemiehandel, VCH), in light of the isolated parallel approaches of the chemical manufacturers to the subject of sustainability, view TfS with some concern.

Ralph Alberti, German Chemical Distribution Association (VCH)

Foundation Of Sustainability

Since the beginning of the '90s, together with the manufacturers, chemical distributors have practiced the Responsible Care Initiative which since then has covered the core sector of the chemical industry – particularly with regard to sustainability before sustainability had even become part of the general discussion.

At the end of the '90s, the chemical industry extended its Safety and Quality Assessment System (SQAS), which is designed for logistics service providers, to include chemical distributors as well, and in the process, created the European Single Assessment Document (ESAD). This provides a uniform evaluation method with which, using standardized questionnaires, independent and specially trained technical experts judge quality, safety and environmental standards.

In the meantime, the program run by the European Chemical Industry Council (CEFIC) over many years has become established and proved its value in chemical distribution. This is illustrated by the fact that about 50 % of the companies that participate in the Responsible Care program of the VCH use ESAD to verify their commitment. Currently, there are about 250 active ESAD assessments.

Looking For Harmony

About 1½ years ago, the first chemical distributors were contacted by the TfS initiative. This initiative for sustainability, developed by some large European chemical manufacturers, stands unfortunately completely isolated from the ESAD system and Responsible Care, which were also initiated by the chemical industry. As a result, at an early stage, the VCH contacted the operators of the TfS initiative with the idea of finding possibilities of a coordination of the initiatives – which ultimately are run by the same protagonists. Together with our European umbrella organization Fecc and Cefic, these efforts have led to an extension of the corresponding ESAD questionnaire to include the missing parts from TfS. The reasoning behind this adaptation was a reciprocal recognition of the initiatives of the chemical manufacturers to avoid double audits and to be able to continue using the tried and tested ESAD system.

Unfortunately – and surprisingly – the manufacturers have, until now, not been able to reconcile the two systems. On the contrary, the chemical distributors are now being pressured to implement both the TfS and ESAD systems parallel to each other although the contents are essentially the same. This means not only answering questionnaires with the same contents, but also carrying out basically the same resource-intensive audits without any additional benefit for sustainability.

Chemical distributors are forced to make the best of a bad job because the protagonists of TfS assert their system with great pressure and short deadlines for their contract partners. This procedure gives rise to the fear that failure to compromise between both systems will, in the end, damage the acceptance of both initiatives. Two parallel systems from the chemical manufacturers with basically the same content are difficult to communicate to the addressees, and they entail the hazard that these systems will cannibalize each other to the detriment of existing structures.

Streamlining Sustainability

As demonstrated by the commitment described at the beginning of this statement, the VCH and its members wholeheartedly support the goal of sustainability and thus, in the end, both initiatives. However, they continue to emphasize the necessity of avoiding a doubling of contents and systems. As suppliers and service providers of the chemical industry as well as the addressees of the systems, the chemical distributors have only very limited possibilities. They can only appeal to the manufacturers as the operators of both ESAD and TfS, in particular also for the sake of sustainability, to find a possibility of mutual recognition in the short term. Today, we already support this process within the realms of possibility.

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Distribution in the Middle East

A Wealth of Opportunities with a Few Obstacles

The Gulf area of the Middle East offers opportunities for international chemical distributors because of its strong economic growth derived from oil wealth. But many multinational chemical distributors, especially those based in Europe, have been steering clear of an area comprising six thriving oil- and gas-producing countries — Saudi Arabia, United Arab Emirates, Qatar, Kuwait, Bahrain and Oman.

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Instead much of the chemicals distribution is done by regional or national companies. Despite the sharp drop in oil prices, they are confident they will continue to benefit from strong demand for chemicals for the next several years.

"Low oil prices are not making much difference to chemicals demand," said Farooq Quaraishi, business development manager at Altek International, Dubai, a manufacturer and distributor of adhesives, emulsion and dispersions. "We are very optimistic about the future and expect good growth across all industries."

Protection From Prices

The fall in oil prices could affect revenues of the governments of the six countries, which maintain a regional union called the Gulf Cooperation Council (GCC). Within the GCC, governments are a vital source of funds for infrastructure, construction and industrial development projects, which are the main drivers of economic growth.

However, most of them are considered to have enough cash reserves to maintain relatively robust growth – at least in the short term before oil prices are likely to rise again.

Gas-rich Qatar is predicted to record growth of 6% this year, while most of the rest of the GCC countries, including Saudi Arabia, are expected to achieve growth of 3%–4% in 2015.

Diversification

In the longer term, the attraction of the region to outside investors is not so much its large hydrocarbon reserves but its plans to diversify its economies, so that they are no longer so financially dependent on oil and gas and bulk petrochemicals.

All the GCC states have moved or are moving their economies downstream into the manufacture of industrial products, many of which are based on petrochemical-derived raw materials.

Dubai, part of the United Arab Emirates, and Bahrain have already been diversifying for many years, so much of their gross domestic products are now coming from non-oil products and services.

Now the rest, in particular Saudi Arabia and Abu Dhabi, the largest of the United Arab Emirates in terms of wealth, are also transforming themselves into much more broadly industrialized economies. Saudi Arabia has the most ambitious plans for downstream industrialization driven by expansions to its big production complexes at Jubail and Yanbu on its eastern and western coasts respectively.

Sadara, a joint venture between Saudi Aramco, the state oil company, and Dow Chemical, is scheduled to start producing this year the first of 3 million tons a year of a range of petrochemicals, such as engineering plastics and other high-performance polymers. Some of these will be used as raw materials for downstream Saudi-based manufacturers.

Adjacent to Sadara is PlasChem, an industrial park that will be making plastics and chemicals for the manufacture of automotive components, pharmaceuticals, water treatment materials and chemicals, construction materials and specialty films.

At Yanbu, which is already one of the world's biggest refining sites, Saudi Basic Industries Corporation (SABIC) is planning an enormous oil-to-chemicals project. It will create around 100,000 jobs through the downstream manufacture of products for future priority sectors in Saudi Arabia including electrical equipment, automobiles and their accessories, medical products, and packaging.

The conversion of the Saudi and the other GCC hydrocarbons-reliant economies to ones with a relatively wide manufacturing base will inevitably stimulate a growing demand for specialty and high-value chemicals, many of them produced outside the region.

Yet multinational chemicals distributors, even those with strategies to expand in emerging economies, are continuing to avoid investing in a significant presence in the GCC.

Some Predict Slow Growth

Germany-based Brenntag, the world's No.1 chemical distributor, has a presence in most of the major regions in the world, so around a third of its sales come from emerging economies. Brenntag has only a representative office covering the GCC countries, although it is considering a larger operation in the area.

"(We have) a long history of customer and supplier relationships in the region, initially as an export market and for purchasing products which are often distributed into our worldwide network," said Steven Holland, Brenntag's chief executive. "In the last two years we have established a representative office, which can be interpreted as the first step to a longer-term expansion in the region."

Biesterfeld, in Hamburg, a leading international distributor of specialty and high performance chemicals also with emerging countries accounting for a third of its sales, has recently postponed opening a GCC office after thinking for a few years about moving into the region.

"The area is still interesting for us, but there are other regions, which are more interesting and fit better into our strategy," Thomas Arnold, Biesterfeld's chief executive, told CHEManager International. "For us, it's important to find the right partner and to build up new business combined with the support by our suppliers. We believe in the long-term growth of the Gulf region, but we do not see it in the next few years. In the near- and middle-term we expect still

a stronger sale of commodities, while there will be a slow increasing demand for specialty chemicals."

Global Versus Local

Among the top international distributors, Univar is one with a large presence in the region with an office and laboratories in Dubai's Jebel Ali Free Zone (Jafza), the world's largest free zone with over 7,000 companies. Many of these are re-exporting products to GCC countries coming through the adjacent Jebel Ali port, the Middle East's largest, whose expansion plans could make it the world's biggest port.

Manuchar, Antwerp, and Jebsen & Jessen, Singapore, are among other multinational distributors with a base in Dubai, now well-established as a strategic hub serving not just the GCC area but also the wider Middle East, southern Asia and eastern Africa.

With international distributors having a relatively small share of the GCC chemicals market, many of the local companies dominating the chemicals distribution sector are manufacturers with distribution businesses.

The biggest dedicated distributor in the region is the Dubai-based Petrochem Middle East (PME), which handles 700,000 tons of products annually with sales of around $600 million. These are mainly commodity petrochemicals but also include specialty chemicals such as pharmaceuticals, coatings and colorants.

Another major regional distributor is REDA Group of Saudi Arabia, which has been expanding internationally into specialty sectors such as oilfield chemicals.

A barrier for non-GCC international distributors is the legal requirement that outside companies, other than those based in free zones like Jafza, must operate through local partners.

Local Connections

Another possible difficulty is the necessity for close ties with local customers, which is a reason why a lot of GCC chemicals distribution is done by manufacturers. "Distribution here is different to that in Europe," Quaraishi said. "The distributor needs to get close to the customer, and being a manufacturer as well helps him do that."

US-based Univar is both a distributor and formulator of chemicals in the area after opening a laboratory two years ago in Dubai for making personal care and industrial cleaning products. "Being a formulator differentiates us from other distributors because our relationship with customers is targeted on selling them solutions," said Matthew Howard, manager of Univar's Dubai-based operation. "We can develop products to suit their specific needs, which saves them a lot of development time."

> "Multinational distributors are avoiding the oil-rich Gulf while regional distributors thrive."

Univar last year formed a joint venture with E.A. Juffali & Brothers, a Saudi conglomerate that is both a manufacturer and distributor. The business, based in Saudi Arabia, will be selling not only personal care and cleaner products but also chemicals for oil and gas and food and coatings production.

Land Logistics

Poor inland logistics is considered by some international distributors to be another obstacle to expansion in the region. Logistics are centered on the area's ports so that products tend to be transported by sea from one GCC country to another. Until recently it was cheaper and easier to ship bulk chemicals from Saudi Arabia's western coast for re-export from Europe to a location on the country's eastern coast.

However, these deficiencies are being put right by the construction of roads and significantly by the building of both domestic and cross-border rail networks. The United Arab Emirates is building a 1,200-kilometer network across its emirates, which will link up with networks in Saudi Arabia and Oman. Saudi Arabia is planning to invest $45 billion on a network that will include a north-south railway connecting its inland industrial areas with its ports.

Ultimately the region's governments hope there will be a GCC rail network run by a GCC rail company. But like with many of the plans for industrial diversification, this will be a long-term objective, which multinational chemical distributors will have to wait patiently to be realized.

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‘Supply Chains are 3-Dimensional Networks’

How Collaborative Systems Can Help Reduce Complexity and Enhance Performance

Because of a rapidly changing world of business and an increase of regulations, the pharmaceutical industry must find new ways to serve patients. CHEManager Distribution & Logistics asked Diane Palmquist, vice president of manufacturing industry solutions, and Boris Felgendreher, director of marketing EMEA, both with GT Nexus, how pharmaceutical companies can face these challenges best.

Boris Felgendreher, director of marketing EMEA, GT Nexus

Diane Palmquist, vice president of manufacturing industry solutions, GT Nexus

CHEManager: Ms Palmquist, from your perspective what are the main topics for pharmaceutical companies looking at logistics?

D. Palmquist: These are volatile times for pharmaceutical manufacturers. The industry is rapidly changing due to multiple pressures and conditions. Consider the growing list of challenges. Things like new regulations, expiring patents, increased outsourcing, challenges to deliver sustained profitability, tighter margins, risks of counterfeiting and theft.

As brands go off-patent, pharma companies increasingly rely on outsourced active pharmaceutical ingredients (API) and expansion into emerging markets to maintain and potentially grow revenue. That increased reliance on outside manufacturers, however, represents a loss of control — a concept that seems to run counter to tightening regulation.

Drugs are sold worldwide and nearly every big player in the pharmaceutical market takes advantage of global sourcing and global production. What are the main consequences?

D. Palmquist: Outsourcing — and to some extent new acquisitions — shifts more production outside the walls of the company, and as a result, adds new risk. It leaves pharmaceutical companies surrendering a significant amount of control over the manufacturing process in return for lower costs. And it opens the door for diminished transparency throughout the manufacturing cycle.

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Supply-chain safety has to be guaranteed — along the whole supply chain. How do you appraise the EU Directive on Falsified Medicines and, in the US, the Drug Quality and Security Act, to meet these needs? On the other hand, governments of the Mideast, Asia and South America go their own way to regulate the supply chain, and to tackle the problem of counterfeit pharmaceuticals. Don’t you think this will complicate the process even more, seen from a worldwide perspective?

D. Palmquist: Increased regulations such as EU FMD are a necessary response to piracy, counterfeiting and the use of drugs as currency, which left unchecked represent some of the biggest risks to the integrity of a brand. The consumer wants to know that what they’re buying is the real thing. While serialization is a necessary part of ensuring the product is pure, it’s part of a much bigger picture in the fight against these risks.

Looking globally, some $15 billion of API will be exported out of India alone this year. While it may be serialized, it doesn’t mean there’s no possibility for drugs to leak in and out of the supply chain. Pharma is global. Regulations aren’t. The same rules that apply in the EU don’t directly affect countries in South America. Manufacturing and distribution go well beyond political boundaries, however, and manufacturers are responsible

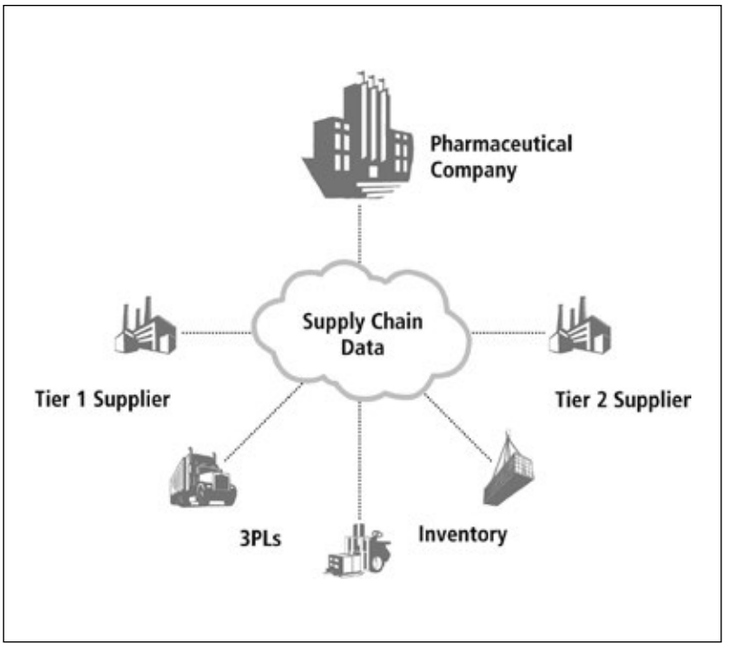
for playing by the rules in whatever geography they operate.

Under these circumstances and with these demands: Will it be possible for pharmaceutical global players to manage their supply chains appropriately?

B. Felgendreher: At the heart of these challenges around visibility, track-and-trace or serialization is connectivity and collaboration. Pharmaceutical companies today tend to rely on traditional hosted software, or ERP (enterprise resource planning) tools. These do an excellent job of connecting people, sharing data and delivering visibility within the four walls of the business. This approach is ideal for looking inside of a business. The challenge pharmaceutical companies face as outsourcing increases and supply chains become more complex is that production moves beyond the outstretched arms of ERP.

Suppliers, factories, logistics providers, customs agents and numerous other parties that touch every transaction are on the outside of business. Pharmaceutical companies have spent years trying to add on or extend their ERP systems to connect supply-chain partners. EDI and portals are single-point connections for trading partners. But this model is unsustainable as the numbers of trading partners grow, with multiple layers of suppliers in different regions, facing different regulations and requirements. Many pharmaceutical companies operate five, 10 or 20 different ERP instances — varying by region. This raises complexity and makes it harder to have true end-to-end supply-chain visibility. A company, in this instance, may find itself bidding or competing against itself in areas such as goods sourcing or freight procurement. The company also loses some of its buying leverage by operating and ordering in a splintered, fragmented environment.

Supply-chain visibility, traceability and connectivity are not bolt-on projects. No single solution addresses this challenge. Rather, it requires a new approach — a rewiring of the underpinnings of connections between a pharmaceutical company and its trading partners. Why and how could a collaborative system be the answer to meet the needs of complexity?



B. Felgendreher: A supply chain is not linear, but rather a 3-dimensional network of networks. The pharmaceutical company sits at the middle with hundreds of surrounding nodes that are also interconnected. A point-to-point approach here is inadequate.

> "Tighter collaboration with partners, bringing greater visibility into the supply chain."
>
> Diane Palmquist, vice president of manufacturing industry solutions, GT Nexus

Rather, what is needed is a new infrastructure that connects all of the nodes not one at a time, but simultaneously, as a single network. A single global network can integrate all of the ERP systems, trading partners, and most importantly, the data that moves between them. With this foundation, the idea of supply-chain visibility becomes a reality.

Pharmaceutical companies can see beyond their tier one suppliers into tiers two and three. Black holes that once existed between trading partners are eliminated through visibility into all transaction documents and interactions. Pharmaceutical companies can know where their goods are and where they've been. This makes track-and-trace and serialization capabilities achievable. But it also opens new doors to operating smarter and with more agility. With visibility and data tied into parties and processes throughout the network, pharmaceutical companies can know their true cost to serve a particular customer segment. They can assess new market opportunities with a clear view.

What will be the preconditions — also technical — to run such a system?

B. Felgendreher: Compared to, let's say, a large-scale ERP implementation project that takes multiple years and an expensive army of consultants to manage, connecting a pharmaceutical company and its supply-chain partners to a cloud-based network is less complex, less time-consuming and a lot less expensive. But most importantly, there is no need for large upfront investments in any kind of IT hardware or software.

In a cloud-based network, both hardware and software is run in the cloud. Every partner on the network is also on the same instance of software code. There are no licenses or upgrades to be managed. In short, the technology barrier is a lot lower compared with traditional enterprise software systems. That's part of the reason why we are seeing such a rapid adoption of cloud networks.

We learned supply-chain processes are much more transparent and easier to handle in a cloud-based system, but are they as safe as in isolated, local ERP systems?

B. Felgendreher: Safety is always a concern, not only in pharma, but in other verticals as well. When it comes to processes and data across the extended ecosystem of any company, the question of safety and security takes on an especially challenging dimension. Today an estimated 80% of supply-chain data is generated outside the four walls and therefore outside the reach of the individual organization. More and more companies consider that an intolerable security risk.

If sensitive data is scattered across the ecosystem of partners, companies can't properly control the access to this data. The more secure approach in this scenario is to move all the data away from the insecure periphery of the network and into the center where all the state-of-the-art security measures can be applied to safeguard the data. Today's world-class cloud supply-chain networks are considered safer than isolated ERP systems.

Is a collaborative system indeed a win-win situation for all the partners of the supply chain?

D. Palmquist: The pharmaceutical industry faces numerous headwinds: Serialization, patent expiration, product safety, assurance of supply, and counterfeiting — to name a few. The foundation to addressing each of these challenges is tighter collaboration with partners, bringing greater visibility into the supply chain. Working in low-cost markets is a big part of business in the coming years. In the past, it was just about getting goods delivered. Margins were so high on on-patent drugs that they could afford to skip over the granular details around cost to serve markets and segments. But growth opportunities are limited today, and pharmaceutical companies have to keep a tight handle on costs, margins and customer demands.

> "Black holes that once existed between trading partners are eliminated."
>
> Boris Felgendreher, director of marketing EMEA, GT Nexus

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No Prospective for a Global Solution

Assessing Track-and-Trace and Serialization Legislation for Life Science Companies

Track-and-trace and serialization legislation for life science companies is gaining momentum around the world. Supply-chain leaders and operations managers must consider compliance with new legislation while examining the broader business facilitating opportunities.

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Healthcare delivery providers and manufacturers are working together to develop end-to-end, value-based supply chains. At the same time, global track-and-trace and serialization laws are truly embracing the principles of end-to-end supply chains. Supply-chain leaders and operations managers must understand the urgency to comply with these new laws. This also presents opportunities to innovate across other supply-chain processes and form more direct relationships with patients, which can improve demand planning, brand reputation and profit margins.

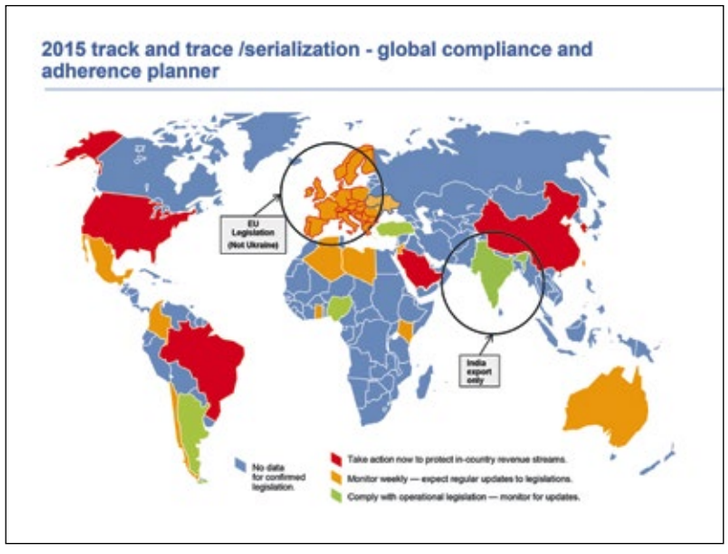
The global proliferation of counterfeit pharmaceuticals that pose a serious potential threat to patients has recently led to a significant increase in mandates for track-and-trace and serialization. High levels of theft, diversion, fraud and goods lost in transit adversely affect supply-chain performance, revenue and brand reputation.

Supply-chain stakeholders and regulatory bodies have been working together to develop mandates and technology platforms to support these track-and-trace and serialization processes. In Europe, Africa and parts of Asia, product authentication is now the primary mode of protecting patients.

With no global governance models in place, individual country laws have evolved independently and become fragmented. These laws have staggered compliance time frames, including some with requirements for this year. To help our clients understand their obligations, Gartner has prepared research notes — highlighted below — to explain the legislation.

Worldwide

In "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, Worldwide," Gartner provides a broad overview of emerging laws, which is further expanded upon in a series of research notes focused on individual regions. Brazil, China, Saudi Arabia, South Korea and the US all require immediate decision-making for deployment of track-and-trace and/or serialization solutions. The legislation in these countries will also affect key supply-chain stakeholders.

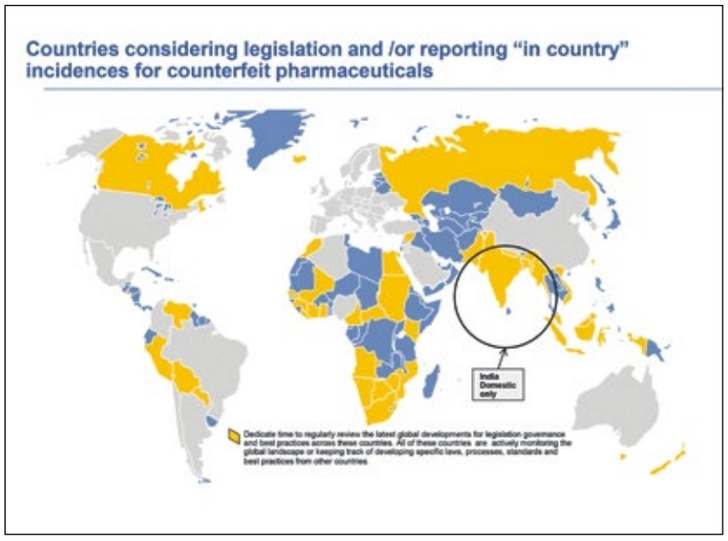


It's important to act quickly and look beyond compliance to explore the wider business benefits that could result from serialization and track-and-trace solutions, such as enhanced supply-chain visibility, optimized packaging changeover times, returns and recalls integration, data complexity reduction, multi-enterprise integration and connectivity across the entire health-care value chain.

Enhanced supply-chain visibility is one of many capabilities for business facilitation through the emerging reference models for product security. "Use Serialization Deployments to Enhance Your End-to-End Supply Chain Visibility" discusses these benefits and capabilities.

United States

The 2013 Drug Supply Chain Security Act marked a turning point for life science companies. They began to look more globally at how the legislation would affect both their near-term and longer-term business strategies for brand protection and track-and-



trace and serialization requirements. "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, United States" explores the implications for manufacturers, re-packagers, wholesale distributors, dispensers and third-party logistics providers.

The law provides a 10-year compliance window for a fully electronic and interoperable network. It also establishes a comprehensive set of near-term mandates as well as longer-term guidance time frames for further ratification of additional capabilities in consultation with stakeholders and industry.

Europe

European serialization mandates are expected in 2018. Europe defines a special classification for "falsified" medicines. The European Commission and industry supply-chain stakeholders have developed laws, processes and a cloud-based technology platform to protect patients from falsified medicines. The focus is on product authentication at points of dispensation, which is different from track-and-trace laws in other countries. Additional requirements and capabilities are being discussed as part of a schedule of delegated acts that will eventually become law. "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, Europe" explores this series of laws, regulations and processes.

Eastern Europe, the Middle East and Turkey

Four countries have established processes in this region. "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, Eastern Europe, the Middle East and Turkey" explores supply-chain operational and strategic requirements and opportunities for these countries. Turkey's Ilaç Takip Sistemi (iTS) is considered the most mature example of deployment of a multi-stakeholder track-and-trace system for pharmaceutical products. As well as ensuring patient safety, iTS can deliver additional business outcomes such as fraud prevention, inventory control, optimized returns and IT interconnectivity.

Saudi Arabia and Jordan have been developing specific guidance legislation, with recommended compliance mandates beginning in March 2015 and 2017, respectively. Ukraine has been drafting legislation and undertaking pilots with key stakeholders and centralized repositories.

> Enhanced supply-chain visibility is one of many capabilities for business facilitation
>
> Andrew Stevens, research director, Gartner UK Limited

South America

"Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, South America" focuses on Brazil's comprehensive phased mandates and immediate compliance requirements in 2015. Argentina has had product security mandates focusing on end-to-end supply-chain traceability and selective tamper-evident product integrity in place since 2011. Evolving operational models in Argentina and Brazil are influencing other countries in the region to develop their own laws and systems to secure drug products.

Asia/Pacific

In "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, Asia/Pacific," we discuss varying levels of development across the region. China has comprehensive legislative requirements, with important compliance milestones set for 2015. China's legislation has differentiated requirements, some of which are unique. Operating principles are full track-and-trace, with stakeholder verification and customer authentication ability. India has regulations covering packaging levels for export markets only. South Korea has legislation in process, with phased compliance requirements that start in 2015.

Africa

In "Assessment of Track-and-Trace and Serialization Legislation for Life Science Companies, Africa," we explain that track-and-trace and serialization laws have yet to emerge in Africa, despite many years of reported seizures and incidents of counterfeit medicines. The region presents unique challenges. Manufacturers and regulators have adopted product authentication through mobile connectivity to patients as the primary way to begin tackling this significant threat to patient safety.

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Combined Transport on the Rise Despite Criticism

Results of the 10th BME Logistics Survey 2014

Despite the damage inflicted upon Deutsche Bahn's image by the recent train drivers' strike, combined transport (CT) is becoming increasingly popular in the economy. Shipping and forwarding agents consider intermodal transport to be a cheap and environmentally friendly alternative to lorries, the major benefits being reliability and planning efficiency. Critics, on the other hand, complain about high prices and poor service, and claim that CT is too slow compared with transport by lorries alone.

Gunnar Gburek,
Association Materials Management, Purchasing and Logistics (BME)

These are the key results of the 10th logistics survey carried out by the Association of Materials Management, Purchasing and Logistics (BME), Frankfurt. In September, 202 buyers of logistics services and freight forwarders from industry and commerce were asked to assess the opportunities and risks of CT. The results of the survey were presented at the 49th BME Symposium Purchasing and Logistics in Berlin. Around 2,000 symposium participants discussed purchasing strategies and supply-chain management solutions to optimize their business processes.

Why CT?

Almost 60% of shipping agents and 85% of forwarding agents would like to expand their CT operations. Whereas just 36% of those surveyed in 2011 believed that intermodal CT would play an increasingly important role, this had grown to 58% in 2014. The reasons for this are increasing road congestion, an impending shortage of drivers and the poor environmental performance of lorries. Furthermore, rail has proved itself to be a competitive alternative in seaport-hinterland transport, with most ports now heavily reliant on this.

A third of respondents also consider the so-called 44-ton regulation to be a decisive factor. This allowed each vehicle to carry four metric tons more than usual during pre- and post-rail-road haulage. Shipping agents also consider CT to be a cheap (78% of respondents) and environmentally friendly (64%) alternative to lorries.

However, survey participants who are already making intensive use of CT were also critical of it. Half of respondents still feel unsatisfied with the short-notice information about the status of trains and shipments (currently 49% compared with 52% in 2011). This is seen as a clear disadvantage compared with road transport, which offers reliable tracking and tracing across the entire region. Despite this, in 2014 the number of complaints regarding punctuality had been halved from 43% in 2011. Although they complain about CT's lack of flexibility, 70% of shipping agents use it. Three years ago this figure was already at 67%. Not much has changed in comparison to lorries here.

Why Not CT?

Not all companies use CT. They consistently point out that CT could be quicker. However, the latest survey has identified an improvement in this respect: In its latest survey, the BME identified that 44% complained about CT being too slow compared with 54% three years ago. Nevertheless, this consistently high number makes it clear that CT has still not managed to shed its image as a slow and sedate mode of transport, despite it not having to contend with traffic congestion and Sunday driving bans.

Almost 10% more than three years ago — 35% — state that they do not use CT because the prices are too high. This is the result of rail tariffs being raised almost every year while lorry prices generally remain constant. Of all respondents, 38% criticized the poor rail service compared with just 30% in 2011. Of these, 33% say the reason is that the nearest CT terminal is too far away. By way of comparison, this was just 24% in 2011. Given that neither of these can be objectively verified, since the number of both trains and terminals has significantly increased in recent years, it only serves to underline the poor reputation of the railway.

Of shipping agents in the survey, 29% confirmed that their potential transport distances are too short. By way of comparison, this was 38% three years ago. This is backed up by statistics, as the average transport distance

is constantly on the rise. This in turn will benefit CT in particular. All of these figures illustrate that there is still a substantial need for rail transport.

Time For a Policy Change

Another survey revealed that shipping agents (85%) and service providers (96%) agree that there should be ongoing political efforts to shift freight traffic toward rail/CT. This should be seen as a desire from those involved to receive more political support rather than renewed regulation of the transport market, which in the past did more to damage the railways than make use of them.

Around 63% of respondents stated "if the gross train weight of 44 t for CT were to rise, this would become an even more attractive option." This appears to be very important for some sectors; however, the permissible weights across all forms of transport are actually experiencing a slight decrease.

"In the medium-term, only trailers and swap bodies that can also be used in CT should be permitted in road transport," according to 53% of respondents. Many seem to favor this method, despite the fact that systems from the likes of Cargobeamer or Nikrasa already can lift onto the rails trailers that can't be lifted by cranes. However, lifting with cranes also means a loss of tonnage and is therefore criticized by service providers. There must be political intervention here to offset the loss of tonnage with new permissible weights.

Shipping Agents' Influence

More than half of shipping agents specify the mode of transport to be used by the service provider. More than a third leave it up to the service providers to decide, with only 12% demanding that CT be used. Of all respondents, 70% claim that they possess the necessary expertise for tenders that do not specify a means of transport. Just under 8% obtain external help, and 15% wish to expand their own knowledge of this through training and the recruitment of competent employees.

Increased Prices Expected

Last but not least, BME examined the development of transport prices. If the estimations of respondents are correct, in 2015 the German economy will have to deal with higher carriage costs. More than half consider rising freight prices to be a real possibility, and this applies to CT as well. Of forwarding agents, 54% envisage a price increase, whereas this figure is 34% for buyers of logistics services. Nearly half of haulage companies and 41% of shipping agents predict higher prices for freight traffic by lorry. Nearly 30% of service providers and 42% of shipping agents believe that maritime transport will become more expensive. Only inland shipping seems to find itself in calm waters, with less than a quarter of respondents expecting higher prices.

A Bright Future

The current BME study shows that CT still has a great deal of potential and therefore a bright future. Shipping agents and service providers certainly recognize the negative aspects of this, however, almost all of them have a positive attitude toward CT. According to many survey participants, there would soon be a significant increase in the amount of long-haul transport by rail if the corresponding policies were adjusted in its favor. BME was surprised by the number of participants expecting higher prices across the board in 2015. It is clear that numerous market players envisage a favorable economic trend, with scarcer transport capacities leading to increased prices.

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Maximum Safety through Consistent Quality Management

Pharma Logistics: EU Directive on GDP Affects Entire Supply Chain

The amended EU directive on good distribution practice (GDP) has been in force since 2013. It transfers many principles familiar from pharmaceutical manufacturing to the distribution of medicinal products. The demands on corresponding pharma logistics processes and transport security are increasing for pharmaceutical manufacturers and logistics providers alike. Safety and GDP-compliant pharmaceutical transports are wholly dependent on consistent quality management — as has clearly been shown since implementation of the GDP amendment.

Christian Specht, European Institute for Pharma Logistics (EIPL)

To ensure long-term successful quality assurance, it is essential to audit logistics processes, to implement quality management structures, and to undertake regular GDP training. As the shipper, pharmaceutical manufacturers generally initiate the first audit of their logistics providers. Increasing numbers of pharmaceutical carriers, however, are also performing audits on their own initiative. Specialists like the European Institute for Pharma Logistics (EIPL), Korntal-Münchingen, Germany, offer external support for auditing, qualification and GDP training.

The current version of the GDP guideline has been in force since November 2013. In principle, the GDP affects the entire logistics chain: first, the pharmaceutical companies and shippers; second, the wholesalers and distributors; and third, the pharma logistics firms, who are responsible for safe transport of the sensitive goods to the end customer.

The shippers have to ensure that they (if they have their own fleet of vehicles), but especially their external logistics providers, can prove use of GDP-compliant processes. Logistics firms must prove they have the right equipment, trained personnel and compliant pharma logistics processes. Let us focus on pharma transports.

Vehicle Qualification

Once processes are clearly defined and communicated within the company, the next step is to audit the vehicle fleet to ascertain whether the vehicles (still) comply with the latest pharma transport criteria. External consultants also assist carriers in this area.

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The first step is to create a specification defining requirements, as part of design qualification (DQ). Equipment on pharma trailers includes, for example, three-point-calibrated temperature sensors, door contact locks and refrigeration units for multi-chamber systems. If the refrigerated vehicle is already built, it is checked to ascertain whether the necessary elements have been installed correctly (installation qualification, IQ) and are also working properly (operational qualification, OQ). Once the vehicle is operational, the performance qualification (PQ) is undertaken, which checks the system in operation.

Best-Practice Example: IJS Global

With around 600 employees, IJS Global is an international logistics provider with customers in over 50 countries. Its specialties include pharma logistics in multimodal, temperature-controlled transports — with a focus on airfreight, a particularly sensitive sector with numerous security regulations. Because of this focus, the GDP amendment resulted in a few optimization tasks along the supply chain.

The pharma logistics experts from EIPL were brought in to analyze processes and determine specific actions needed. The aim is full GDP certification for all pharma logistics activities.

"Naturally, we were able to build on some existing internal standards," said Christoph Schneider, head of IJS Global's German main branch in Kelsterbach near Frankfurt am Main. "Nevertheless, it quickly became clear following the first inventory that documentation and internal communication to staff needed to be upgraded."

Next, IJS and EIPL defined 12 theme areas for quality management, which are either ISO- (International Organization for Standardization) or GDP-relevant. The partners created new procedures and clarified responsibilities where existing QM processes were partly or completely insufficient for GDP requirements.

"For example, contracts with customers and suppliers need to be clear, to ensure precise definition of the

areas of responsibility," Schneider said. "Specifically, this means who evaluates the data logger from the temperature-controlled transport and how the person responsible proves the required temperature range was maintained throughout the shipping process."

Here the IJS Global branch manager noted that the temperature controls performed by logistics firms for HGV transports are now a realistic option, which is completely in contrast to air transports with dispatching and receiving stations where the local infrastructure is incomplete or missing. This is because the goods are on the airlines' or the airport operator's territory as soon as the shipment is handed over to the airline — which can lead to difficult control conditions as a result.

Schneider: "We are also working with our partners from the individual airlines, though, on solutions to facilitate appropriate documentation and an optimum Cool Chain — using fact sheets for airlines or SOPs, for example, which are coordinated globally with all supply-chain participants."

Once the documentation processes were optimized, IJS Global needed to train its staff to use the new additional workflows — also with crucial external support. There have been two in-house training sessions to date, in which the external pharma logistics experts explained not only the GDP rules to the team, but also specific realization in their own firm, including the newly created responsibilities, documentation requirements, conduct in the event of deviations, worst-case scenarios, etc. This regular training is a central component of the firm's QM strategy.

GDP Amendment 2013

The key legislation for pharma transports in Europe is the EU GDP directive, more precisely the Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use. The 2013 amended version of the GDP guidelines is derived from the global GDP guidelines of the World Health Organization, which has also published Good Trade and Distribution Practices for Pharmaceutical Starting Materials (GTDP). The final version of the GDP guidelines has been restructured compared with the draft version. The directive is divided into the following 10 chapters: Quality Management, Personnel, Premises and Equipment, Documentation, Production, Quality Control, Outsourced Activities, Contract Manufacture and Analysis, Complaints and Product Recall, and Self-Inspection.

EU directives like good manufacturing practice (GMP) and good distribution practice (GDP) set the legal standards — transposed into national law in Germany by legislation including the Ordinance on the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients (AMWHV). The GDP amendment applies the known principles of good manufacturing practices from pharmaceutical manufacturing to the transport of medicinal products. Specifically this means that continuous process controls — particularly with regard to temperature — are subject to much tighter regulation. This means that monitoring and documentation of transports also take on a much greater significance.

Quality Of Pharma Transports

The GDP amendment enables pharmaceutical companies to consolidate and strengthen the requirements they place on logistics providers in terms of transport quality and safety. This requires clear processes; consistent quality management, including cleaner documentation; GDP-compliant, suitable vehicles; and correspondingly trained personnel.

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Navigating GDP in Europe

A Close Look at the Implementation of the EU Good Distribution Guideline

The revised EU Good Distribution Guideline went live almost two years ago. In the meantime many national health authorities and associated bodies have worked on guidance documents and codes of conduct to provide support and assistance in implementing it. We all know that the EU GDP Guideline leaves room for interpretation. The publication of frequently asked questions (FAQ) is one prominent way to share the national view.

Dr Nicola Spiggelkoetter, Knowledge & Support

In an additional layer, national attitudes can be taken from various codes of conduct. In this short paper we will concentrate on Germany, Austria, France, the United Kingdom and finally Ireland and their national views on its implementation.

Germany

Up to now Germany has not published any code of conduct or FAQ, but a couple of publications by organizations reflect current opinions. In Germany the risk-based approach is favored when addressing key issues of the EU GDP Guideline.

Let us take transportation as an example: Long-distance and last-mile transportation routes (from wholesale distributors to local pharmacies) are considered to be subject to different levels of risk. Especially for short last-mile routes, it is assumed that for 15 °C to 25 °C products no additional technical equipment for cooling is required to maintain ambient conditions. In case of temperature excursions, most ambient products are considered to be robust enough to tolerate such excursions and that negative impacts on the pharmaceutical quality will be the exception rather than the rule.

> "EU GDP Guideline leaves room for interpretation."
>
> Dr Nicola Spiggelkoetter, Knowledge & Support

Of course, some parties favor a different understanding; some have learned their lessons from inspections and audits. These parties strictly respect the labeled storage conditions during transit. The fundamental question is: Why should last-mile transports be treated in a different way?

Austria

In 2014 the Phago (Association of Austrian Wholesale Distributors) and the Pharmig (Association of the Austrian Pharmaceutical Industry) published an updated codex, defining non-binding requirements for the national transport of pharmaceutical preparations, for transports within Austria.

Looking for statements on the transport temperature we find the following: Short-term deviations of the temperature range 2 °C to 30 °C (up to 12 h) are accepted for ambient 15 °C to 25 °C products. The authors, however, admit that even this broad temperature corridor cannot be maintained without any technical support and adaptation of the processes concerned, in particular when standard courier service providers are engaged. The credo of voices critical of this time span is that 12 h by no means are short.

United Kingdom

The MHRA (Medicines and Healthcare Products Regulatory Agency) treads a different path; it has published FAQ on its website. Let's first focus on storage during transit. In the eyes of the MHRA, 36 h are the deadline, for longer storage a relevant wholesale distribution authorization is required. In Ireland the deadline is 48 h; in Germany 24 h, although in Germany interpretation is not stated explicitly in any document. The discussion includes annotations on mean kinetic temperature (MKT) and its role on handling deviations. MKT should not serve as an excuse for poor logistics. Deviations from storage or transport temperature can be evaluated only on the basis of valid data (temperature records and stability data).

France

In France the path to the revised EU GDP Guideline was already prepared by the publication of the "Bonne Pratique de Distribution en Gros" in 2000. In Chapter 1.2 g) we read the following: "Les conditions de conservation sont respectées à tout moment, y compris au cours du transport."

This statement clearly indicates the assumption that storage and transport temperature should be treated identically, thus when the storage temperature is fixed at 15 °C to 25 °C, the same range should be respected during transportation, as stated in Chapter 5.13, Deliveries.

Ireland

The HPRA Ireland (Health Products Regulatory Authority) published its GDP guidance document "Guide to Good Distribution Practice of Medicinal Products for Human Use" in April 2014. It goes through the guideline chapter by chapter. It also includes sales representatives' and doctors' samples.

Lessons to be Learned

After the EU GDP Guideline came into force in November 2013, 2014 was the year of interpretations and codes of conduct or FAQ. We presume that in 2015 we will learn a lot from the GDP audits and findings of non-compliance — and the effect this will have on pharma logistics.

For detailed literature contact the author directly.

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Trifleet Offers New Swaps

Trifleet Leasing has added new lightweight frame swap body tank containers to its fleet. The lessor claims to be the first leasing company to offer these special swaps. Within the coming 12 months a total of 45 lightweight swap tank containers will be added to the fleet; each one has a volume of 35,000 l and four sets of the new V-Aerofoil baffle inside.

The new swaps have a lower tare weight resulting from a robust container frame, which is constructed in such a way that it only adds mass where and when needed for strength and leaves mass out where it is not required. In this way, the tare weight can be reduced by up to 10% for a swap body.

The exact weight reduction per swap depends on size and extras. In general, swap tank containers are used as a cost-effective way for short distance transport of goods via road, rail and sea; in particular for light cargoes of chemical and food grade companies in the European market. Interest in swap containers is also growing in China and the Middle East.

Compared to standard ISO tank containers, swaps have bigger tanks and therefore offer more tank capacity. The new lightweight swaps offer even more pay load, resulting in more volume per transport and less transport costs per liter. With regards to environmental impact, the new swap tanks can lower the amount of transport necessary in the long run, and therefore reduce congestion and emission.

The process of engineering to save weight on swap tank containers is difficult, given the many rules and high-quality requirements regarding the lifetime of a tank. The new swap design is manufactured by Welfit Oddy in South Africa.

„At Trifleet Leasing, we are committed to providing innovative tank containers that are ideally suited to our customers' requirements," says Philip van Rooijen, managing director of Trifleet Leasing. (rk)

Tank Containers for Specific Customer Demands

Custom-made Solutions Transport, Store Liquids

Tank container use is common for transport or storage of liquid chemicals. A wide range of different tank containers is available for nearly every purpose. Very often, chemical companies rent tank containers only to be sure that the equipment is in top shape or because they have a very special demand.

Tank containers with special insulation and heating are used, for example, to transport glue. Producers rent these containers to transport products that are required for manufacturing the end product. The medium needs to be transported and processed within a certain temperature range. The site where the medium is manufactured and the one where it is to be processed are in different countries, and considerable distances need to be covered, mostly by rail. The temperature needs to be kept relatively constant over a certain period of time to avoid unnecessary and costly reheating of the container. A positioning system that tracks its location and temperature makes it possible to rectify potential delays swiftly.

The rental of tank containers for liquid products used in the chemical industry such as the one described above has been the core business of TWS for more than 25 years. It also offers containers for liquid foodstuffs. All tank containers are standardly equipped with steam heaters, walkways and ladders, collapsible handrails, man lids, and spout cabinets. If required, electric heating can be retrofitted. Different units are available with superior linings, such as Saekaphen or Chemline, as well as rubber linings, specifically for corrosive or ultrapure products.

Custom-made Solutions

Besides offering standard equipment, TWS has always had a special interest in providing custom-made solutions to meet specific customer demands, such as reefer tank containers. The special reefer tank containers for the chemical or foodstuff industries allow the liquid products in tank containers to be cooled to -20 °C and heated up to 50 to 80 °C, depending on the type (electrical or diesel). Some tank containers are equipped with an agitator or cleaning-in-place (CIP) units.

The capability of the cooling/heating device is 7,000 W. There are stream channels, and vacuum rings are all around the container, including front bottom and rear bottom as well as insulated tubes for the cooling liquid and complete foam insulation for the least possible temperature loss. Maintaining an almost-constant temperature also reduces energy costs.

The tank containers are equipped with certain specialties, such as a complete discharge compartment with cover and bottom for perfect cleanness of the valve, completely to close box for product samples, adapter pieces or similar, insulated man lid with 500-mm manhole, box to close for nitrogen line, surge tank for the cooling liquid glycol, and a digital thermometer.

The cooling device can be handled simply because it is installed at the rear bottom for setting the desired product temperature as well as for error readouts (display flashes). Lead-sealing is certainly possible.

Worldwide Tank Container Rental

When TWS began, its main business field was within Europe, but the company expanded quite well and operates worldwide today. In January, TWS established an office in China.

The company will once again present its range of services as an expert on tank container technology at booth B4 225/322 in Hall B4 in the ITCO Village at the Munich trade fair Transport Logistic.

www.tws-gmbh.de

Chemical or foodstuff industry: Special reefer tank containers allow the liquid products to be cooled to –20 °C and heated up to 50 to 80 °C, depending on the type.


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